



DEPARTMENT OF HEALTH AND HUMAN SERVICES

917264  
Food and Drug Administration  
Cincinnati District Office  
Central Region  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
Telephone: (513) 679-2700

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

**WARNING LETTER CIN-WL-01-188**

September 14, 2001

Darl R. Harkleroad  
President  
Classic Delight Inc.  
310 South Park Drive  
St. Marys, Ohio 45885

Dear Mr. Harkleroad:

We inspected your firm located at 310 South Park Drive, St. Marys, Ohio, on October 11 through 17, 2000. Our inspection found serious deviations from the Seafood Hazard Analysis and Critical Control Points (HACCP) Regulations (21 CFR Part 123). These deviations, which were previously brought to your attention, cause your Tuna Salad Sandwiches in Modified Atmospheric Packaging to be adulterated under Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the Seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations are as follows:

You must verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, to comply with 21 CFR Part 123.8 (a). The HACCP plan developed by your firm correctly identified Clostridium botulinum as a hazard and correctly listed final storage as a critical control point. The plan does not, however, include controls sufficient to prevent the formation of C. botulinum during the shelf life of the product, e.g. product distribution and consumer storage under normal and moderate abuse conditions. The hazard analysis should consider each step of the process, product storage and distribution and final preparation and use by the consumer. The lack of controls in the plan to prevent toxin formation past finished product storage in your plant confirms you have not verified the adequacy of your HACCP plan.

You have failed to list an adequate monitoring procedure to control the hazard of C. botulinum in your HACCP plan for tuna sandwiches in modified atmospheric packaging.

You did not respond to our December 16, 1999 letter requesting further information about the safety of your tuna salad sandwich in modified atmospheric packaging with respect to C. botulinum. You have provided no evidence your product can be safely held refrigerated and there is no expiration date on the package indicating how long the product can be safely held once it is thawed. Although you claim the

tuna salad is acidified, you have provided us with no evidence that when the salad is incorporated into a sandwich, the sandwich can sustain a pH below 4.6. Your HACCP plan for tuna salad sandwiches packaged in modified atmospheric packaging must address the hazard of C. botulinum unless the product is intended to be maintained in a frozen state throughout distribution and is so labeled.

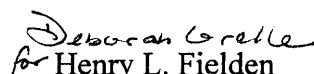
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product (s) and/or enjoin your firm from operating.

Please respond in writing within three weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should consider including any studies conducted to demonstrate there is no growth of C. botulinum spores in your product throughout the intended refrigerated shelf life. Your response should also include documentation of your corrections, such as a copy of your revised HACCP plan, monitoring procedures, and copies of labels revised to state "KEEP FROZEN UNTIL USE" indicating you intend for this product to be maintained in a frozen state throughout distribution. If you can not complete all corrections before you respond, we expect that you to explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations (21 CFR Part 123), and the Good Manufacturing regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Leonard J. Farr, Compliance Officer, 6751 Steger Drive, Cincinnati, Ohio 45237-3097. If you have any questions regarding the seafood HACCP regulations, please contact Mr. Farr at (513) 679-2700 extension 164.

Sincerely,

  
for Henry L. Fielden  
District Director,  
Cincinnati District